of information in the following FDA regulations and forms have been approved by OMB as listed in the following table:

21 CFR part and form	Topic	OMB control No.
1002, 1010, 1040, and form FDA 3632 ...	Reporting and Recordkeeping for Electronic Products—General Requirements	0910–0025

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09380 Filed 5–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2049]

Medical X-Ray Imaging Devices Conformance With International Electrotechnical Commission Standards; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Medical X-Ray Imaging Devices Conformance with IEC Standards.'' This guidance describes FDA's policy regarding the regulation of medical x-ray imaging equipment that is subject to the Federal Food, Drug and Cosmetic Act (FD&C Act) and FDA's regulations that apply to medical devices and electronic products.

DATES: The announcement of the guidance is published in the **Federal Register** on May 8, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–2049 for ''Medical X-Ray Imaging Devices Conformance with IEC Standards.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Medical X-Ray Imaging Devices Conformance with IEC Standards'' to the Office of Policy, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Robert Sauer, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5628, Silver Spring, MD 20993–0002, 301–796–3580.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance describes FDA's policy regarding the regulation of medical x-ray imaging equipment that is subject to the FD&C Act and FDA's regulations that apply to medical devices and electronic products. In this guidance, FDA is seeking to harmonize performance standards prescribed pursuant to section 534 of Subchapter C (Electronic Product Radiation Control (EPRC)) of the FD&C Act (21 U.S.C. 360(kk)) with International Electrotechnical Commission (IEC) standards, where appropriate, to help to ensure streamlined regulatory review of submissions for these products. The guidance also provides recommendations to industry on how to comply with the applicable requirements. FDA has determined that industry conformance to certain IEC standards would provide, at a minimum, the same level of protection of the public health and safety from electronic radiation as certain EPRC regulatory standards. In addition, due to the recent publication of a proposed rule (84 FR 12147) on April 1, 2019, that would, if finalized, eliminate the reporting requirements for x-ray imaging devices, FDA determined that the proposed policy outlined in section 4 of the draft guidance, which stated that x-ray imaging devices that conform to IEC standards would be considered to have met the EPRC reporting requirements, should be removed from the guidance. This decision was made to avoid the confusion inherent in establishing an interim procedure that would shortly be superseded by the final rule. However, as stated in section V. of the guidance, FDA believes that submission of a declaration of conformity to the appropriate standards, and model identification as required by 21 CFR 1002.10(a) and (b), in a product report, would be sufficient to meet the requirements of a product report under 21 CFR 1002.10, thus reducing duplication.

FDA considered comments received on the draft guidance that appeared in the **Federal Register** of August 3, 2016 (81 FR 51201). FDA revised the guidance as appropriate in response to the comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Medical X-Ray Imaging Devices Conformance with IEC Standards.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Persons unable to download an electronic copy of ''Medical X-Ray Imaging Devices Conformance with IEC Standards'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1400014 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

In the **Federal Register** of August 3, 2016 (81 FR 51201), we requested comments on the revision of OMB control number 0910–0025, ''Reporting and Recordkeeping for Electronic Products—General Requirements,'' to adjust the annual reporting burden consistent with the policy in the draft guidance pertaining to reports. However, because this final guidance does not include this policy pertaining to reports (see the Background section), we have determined that the guidance no longer necessitates revisions to OMB control number 0910–0025.

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the following FDA regulations have been approved by OMB as listed in the following table:

21 CFR part	Topic	OMB control No.
807, subpart E	Premarket Notification	0910–0120
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073
1002 through 1050	Reporting and Recordkeeping for Electronic Products—General Requirements	0910–0025

Dated: May 2, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09405 Filed 5–7–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1344]

Policy Clarification for Certain Fluoroscopic Equipment Requirements; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Policy Clarification for Certain Fluoroscopic Equipment Requirements.'' This guidance document intends to clarify FDA's interpretation of certain aspects of the performance standard requirements in FDA's regulations for fluoroscopic equipment.

DATES: The announcement of the guidance is published in the **Federal Register** on May 8, 2019.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows: